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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|---|---|---|---|
| 08/849,525 | 08/29/97 | LANZENDORFER G | 435-WCG |

HM12/0522
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| EXAMINER | |
|---|---|
| SHAREH,S | |
| ART UNIT | PAPER NUMBER |
| 1619 | 22 |

DATE MAILED: 05/22/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

| Office Action Summary | Application No. 08/849,525 | Applicant(s) Lanzendorfer et al |
|---|---|---|
| | Examiner SHAHNAM SHARAREH | Art Unit 1619 |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) ☒ Responsive to communication(s) filed on *Feb 26, 2001* .

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

**Disposition of Claims**

4) ☒ Claim(s) *8, 11-16, and 18* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *8, 11-16, and 18* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

**Application Papers**

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

15) ☐ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

## DETAILED ACTION

Amendment filed on February 26, 2001 has been entered. claims 8, 11-16, 18 are now pending.

### *Response to Arguments*

1. Applicant's arguments with respect to the rejection of claims 8, 13-16, and 18 under 35 U.S.C. 102(b) as being anticipated by Suzuki et al US Patent 5,145,781 have been fully considered but are not found persuasive. Claims 8, 13-16, 18 stand rejected.

Applicant argues that Suzuki is directed to methods of manufacturing alpha-glycosyl rutin and is not directed to any specific formulation of any specific use. Applicant further alleges that Suzuki only teaches 5 properties of alpha-glycosyl rutin and based on such properties he speculates that the alpha-glycosyl rutin would be useful for just about everything under the sun.

In response, Examiner states that claims 14, 18 are directed to cosmetic compositions. Accordingly, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Suzuki disclose pharmaceutical and cosmetic compositions comprising alpha-glycosyl rutin (examples B-5, B-9, B-15). Therefore, Suzuki meets the limitations of instant compositions of claims 14 and 18.

Furthermore, Suzuki et al disclose the use of α- glycosyl rutin as preventative remedy, UV-absorbent, and promoter for healing injury and burn (col 9, line 67-68; col 18, lines 15-18; col 13, lines 65-68; col 14, line 2). Skin injury and burn are clinical conditions manifested by signs of inflammation. In addition, the recitation of "optionally" does not limit the instant formulations to further contain the optional components. Thus, Suzuki discloses all method steps of the instant claims 8, 13, 16. Accordingly, Suzuki et al meet the limitations set forth in the claims 8, 13, and 16.

2. Applicant's arguments with respect to the rejection of claim 14 under 35 U.S.C. 102(b) as being anticipated by Chikawa et al US Patent 5,153,000 have been fully considered. This rejection is withdrawn.

3. Applicant's arguments with respect to the rejection of claims 8, 11-16, 18 under 35 U.S.C. 103(a) as being unpatentable over Nakamura et al US Patent 5,561,116 in view of Whittle US Patent 5,466,452 and Nakanishi et al US Patent 5,008,441 have been fully considered but are not found persuasive. Claims 8, 11-16, 18 stand rejected.

Applicant argues that Nakamura does not specifically teach individual components or the amount of each individual component within the 5% organic or inorganic compounds of Propolis. This argument is not found persuasive, because Nakamura teaches compositions contatining combination of flavonoids. The instant claims are also directed to a combination (one or more) of flavanoids.

Further, the during prosecution of an application Office views the claims in their broadest reasonable interpretation. In the instant case, an cosmetically or pharmacologically effective concentration is viewed as a concentration between the range of 0.001% to 30% per weight of total composition, as recited in page 15 line 18-30 of the specification. Nakamura teaches such concentrations (examples 1-2, claim 9, 15). Nakamura also teaches his composition for treatment of immunopathies (col 7, line 59-61) and in topical ointment or cataplasm formulations (col 8 lines 35-37). Furthermore, determining such concentrations are well within purview of an ordinary skill in the art and ascertainable by conventional methods.

In response to Applicant arguments that Whittle does not teach cosmetically or dermatologically effective concentrations of flavanoids nor a method for the treatment, prophylaxis or prevention of immunosuppression of the skin, Examiner states that the instant claims are directed to methods of treatment OR prophylaxis of immunosuppression of skin by applying a flavonoid to the skin. The combination of cited art meets this limitation. The fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). The combination of cited art teaches effective treatment of an inflammatory response when a flavonoid containing topical product (ointment) is applied to skin, therefore, the source inducing an inflammatory response does not impart patentability of the instant claimed invention.

The cited prior art teach that each of the claimed components of the instant composition is conventionally employed in the art for treating topical inflammatory skin disorders in the same range of concentration as instantly claimed, therefore, it would have been *prima facie* obvious to one of ordinary skilled in the art at the time of invention to employ the instant flavonoids, a cinnamic acid derivative, and an antioxidant components in combination for their known functions and optimize the amount of each additive to provide a compositing having superior anti-inflammatory effects.

Finally, in response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Accordingly, the combined teachings of the cited art must be considered in viewing the rejection.

***Conclusion***

4. No claims are allowed. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh, PharmD whose telephone number is (703) 306-5400. The examiner can normally be reached on Monday to Friday from 8:30 a.m. to 5:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diana Dudash can be reached on 703-308-2328. The fax phone number for this Group is 703-308-4556. Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is 703-308-1235.

*sjs, 5/12/01*